IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

Ernetta Simpson, an individual Plaintiff, vs. Cook Incorporated; Cook Medical Incorporated; Cook Group Incorporated; Cook Medical, LLC, Defendants.	CASE NO. _____ JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Ernetta Simpson, by and through her undersigned attorney, hereby sues defendants Cook Incorporated, Cook Incorporated a/k/a Cook Medical Incorporated, Cook Group Incorporated, Cook Medical, LLC, alleges as follows:

PARTIES

1. Plaintiff Ernetta Simpson (hereinafter "Plaintiff") at all times relevant to this action resided in, continues to reside in, and is a citizen of Macomb County, Michigan.

2. Defendant Cook Incorporated was and is an Indiana corporation authorized and/or doing business in the state of Michigan. At all times relevant to this action, Cook Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold

the inferior vena cava filter ("IVC Filter") known as the Gunther Tulip™ Vena Cava Set (hereinafter "Cook filter") to be implanted in patients throughout the United States, including Michigan. At all times relevant hereto, Defendant Cook Incorporated was registered to do business in Michigan, engaged in business in Michigan, has conducted substantial business activities and derived substantial revenue from within the State of Michigan. This Defendant has also carried on solicitations or service activities in Michigan.

3. Defendant Cook Incorporated is the parent company of Defendant Cook Medical, Incorporated. Defendant Cook Medical Incorporated was and is an Indiana corporation authorized and/or doing business in the state of Michigan. At all times relevant to this action, Cook Medical Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the inferior vena cava filter ("IVC Filter") known as the Gunther Tulip™ Vena Cava Set to be implanted in patients throughout the United States, including Michigan. At all times relevant hereto, Defendant Cook Medical Incorporated was engaged in business in Michigan has conducted substantial business activities and derived substantial revenue from within the State of Michigan. This Defendant has also carried on solicitations or service activities in Michigan.

4. Defendant Cook Group Incorporated was and is an Indiana corporation authorized and/or doing business in the state of Michigan. At all times relevant to this action, Cook Group Incorporated designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and sold the inferior vena cava filter ("IVC Filter") known as the Gunther Tulip ™ Vena Cava Set to be implanted in patients throughout the United States, including Michigan. At all times relevant hereto, Defendant Cook Group Incorporated was engaged in business, has conducted substantial business activities, and derived substantial revenue from within the State of Michigan. This Defendant has also carried on solicitations or service activities in Michigan.

5. Defendant Cook Incorporated is the parent company of Defendant Cook Medical, LLC. Cook Medical, LLC was and is an Indiana limited liability corporation authorized and/or doing business in the state of Michigan. At all times relevant to this action, Cook Medical, LLC designed, set specifications, manufactured, prepared, compounded, assembled, processed, promoted, marketed, distributed, and/or sold the inferior vena cava filter ("IVC Filter") known as the Gunther Tulip ™ Vena Cava Set to be implanted in patients throughout the United States, including Michigan. At all times relevant hereto, Cook Medical, LLC. was registered to do business with the State of Michigan. At all times relevant hereto, Defendant Cook Medical LLC was engaged in business in Michigan, has conducted

substantial business activities and derived substantial revenue from within the State of Michigan. This Defendant has also carried on solicitations or service activities in Michigan.

6. Defendants Cook Incorporated, Cook Incorporated a/k/a Cook Medical Incorporated, Cook Group Incorporated, and Cook Medical, LLC shall be referred to herein individually by name or collectively as the "Cook Defendants."

7. At all times alleged herein, Cook Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

8. At all times herein mentioned, each of the Cook Defendants were the agents, servants, partners, predecessors in interest, and joint venturers of each other, and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.

JURISDICTION AND VENUE

9. Personal jurisdiction is proper pursuant to 28 U.S.C. § 1332. The Cook Defendants have conducted and continue to conduct substantial and systematic business activities related to their IVC filters, including the Gunther Tulip ™ Vena Cava Filter (hereinafter "Cook filter") at issue in this case, in this jurisdiction. Such

activities include, but are not limited to: (a) sales of IVC filters, including the Cook filter at issue in this case, in this jurisdiction; (b) hiring, training, and deploying employees, including managers and sales representatives, in this jurisdiction; (c) advertising and marketing of their IVC filters, including the Cook filter at issue in this case, in this jurisdiction; (d) maintenance of company files and equipment relating to the Cook filter in this case, in this jurisdiction; (e) payment of employee salaries in this jurisdiction; and (f) maintenance of a website directed to all states, including Michigan. Defendant Cook Medical LLC is registered to do business in the State of Michigan. The Cook Defendants also committed tortious acts within the State of Michigan and caused injury to persons or property within the State of Michigan arising out of acts or omissions by the Cook Defendant outside this state at or about the time of the Plaintiff's injury, while the Cook Defendants were engaged in solicitation or service activities within the State of Michigan; and/or, while products, materials, or things processed, serviced, or manufactured by the Cook Defendants were used or consumed within Michigan in the ordinary course of commerce, trade, or use.

10. There is complete diversity between the parties and the amount in controversy exceeds $75,000 exclusive of interest and costs. *See 28 U.S.C. § 1332.*

11. Venue is properly laid pursuant to 28 U.S.C. § 1391(b)(2) and (d), as the Cook Defendants' Cook filter was marketed, sold, implanted and failed in

Macomb County, Michigan and the Defendants are corporations subject to personal jurisdiction in the district.

12. Plaintiff's claims in this action are brought solely under state law. Plaintiff does not herein bring, assert, or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation, or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question under 28 U.S.C. § 1331.

GENERAL FACTUAL ALLEGATIONS

13. Plaintiff brings this case against the Cook Defendants because of serious, life-threatening injuries she suffered as a result of the Cook Defendants' surgically implanted medical device, the Cook Gunther Tulip filter, that was implanted by Herman-Simon Kado, M.D. at St. John Macomb – Oakland Hospital in Madison Heights, Michigan on or about February 2, 2017.

14. Cook Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and sell IVC filters, which are marketed and sold as both permanent and retrievable devices, purportedly to prevent recurrent pulmonary embolism via placement in the vena cava. One such product is the Cook Gunther Tulip IVC filter.

15. Cook Defendants sought Food and Drug Administration ("FDA") clearance to market the Cook Gunther Tulip Filter device and/or its components under Section 510(k) of the Medical Device Amendment.

16. On or about October of 2000, the Cook Defendants obtained FDA clearance to market the Cook Gunther Tulip filter under Section 510(k) of the Medical Device Amendment as a permanent IVC filter.

17. On or about October 31, 2003, the Cook Defendants obtained FDA clearance to market the Cook Gunther Tulip under Section 510(k) of the Medical Device Amendment as a retrievable IVC filter.

18. Section 510(k) allows marketing of medical devices if the manufacturer claims the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of said device. The device is then cleared by the FDA under Section 510(k). The Cook Defendants claimed that the Gunther Tulip filter was substantially equivalent to the Greenfield and LGM Vena Tech IVC filters.

19. An IVC filter, like the Cook Gunther Tulip filter, is a device ostensibly designed and intended to filter blood clots that would otherwise travel from the lower portions of the body to the heart and lungs, resulting in a pulmonary embolism (PE). IVC filters are marketed as being safe to implant, either temporarily or permanently, within the vena cava.

20. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. These thrombi can develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. If the thrombi reach the lungs, they are considered "pulmonary emboli" or PE.

21. An IVC filter, like the Cook Gunther Tulip filter, is ostensibly designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

22. The Gunther Tulip filter has four (4) anchoring struts for fixation with webbed wires (like tulip petals) between each of the anchoring structs.

23. On or about February 2, 2017, Plaintiff was implanted with a Cook Gunther Tulip IVC filter at St. John Macomb – Oakland Hospital in Madison Heights, Michigan by Herman-Simon Kado, M.D. The Cook filter placed in Plaintiff was stated to be appropriate for use as a permanent filter or a retrievable filter.

24. Plaintiff suffered injury as a result of the implant of the Gunther Tulip filter. Specifically, on June 8, 2017, Plaintiff underwent an operation that involved multiple failed attempts to remove the Gunther Tulip filter, however, all attempts at removal were unsuccessful. As a result, Plaintiff is at risk for future progressive

perforations by the Gunther Tulip filter which could further injure adjacent organs, blood vessels, and structures, as well as fracturing of the IVC filter and migration of the Gunther Tulip filter or pieces thereof. The Plaintiff faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical care and monitoring for the rest of her life. It is unknown if the filter can be retrieved by any means other than an open surgical procedure.

25. At all times relevant hereto, the Cook Gunther Tulip filter was widely advertised and promoted by the Cook Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.

26. At all times relevant hereto, the Cook Defendants knew or should have known its retrievable IVC filters were defective and knew that the defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

27. The Cook Defendants failed to disclose to physicians, patients, or Plaintiff that its retrievable IVC filters, including the Gunther Tulip filter, were subject to breakage, collapse, causing thrombus, and/or the appropriate degree of risk of damage to the vena cava wall.

28. At all times relevant hereto, the Cook Defendants continued to promote their retrievable IVC filters, including the Gunther Tulip filter, as safe and effective,

even though the clinical trials that had been performed were not adequate to support long- or short-term efficacy.

29. The Cook Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with its IVC filters, including the Gunther Tulip filter, as aforesaid.

30. The failure of the Cook filter is attributable, in part, to the fact that the Cook retrievable IVC filters, including the Gunther Tulip filter, suffer from a design defect causing the filters to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

31. At all times relevant hereto, the Cook Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Gunther Tulip IVC filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

32. The Gunther Tulip IVC filter was designed, manufactured, distributed, sold, and/or supplied by the Cook Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of the Cook Defendants knowledge of the product's failure and serious adverse events.

33. At all times relevant hereto, the officers and/or directors of the Cook Defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

FRAUDULENT CONCEALMENT

34. The Cook Defendants were and remain under a continuing duty to disclose the true character, quality, and nature of the device that was implanted in Plaintiff, but instead they concealed them. The Cook Defendants' conduct, as described in this complaint, amounts to conduct purposely committed, which they must have realized was dangerous, heedless, and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

35. At all times herein mentioned, the Cook Defendants were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

36. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between the Cook Defendants such that any individuality and separateness between them have ceased and these Cook Defendants are alter egos of one another. Adherence to the fiction of the separate existence of these Cook Defendants as entities distinct from each other will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

37. At all times herein mentioned, the Cook Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

38. At all times herein mentioned, the officers and/or directors of the Cook Defendants named herein participated in, authorized and/or directed the production, marketing, promotion and sale of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

COUNT I
NEGLIGENCE

39. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

40. At all times relevant to this cause of action, the Cook Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Gunther Tulip filter.

41. The Cook Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed, and sold the Gunther Tulip filter that was implanted in Plaintiff.

42. The Cook Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Gunther Tulip filter so as to avoid exposing others, including Plaintiff, to foreseeable and unreasonable risks of harm.

43. The Cook Defendants knew or should have known that the Gunther Tulip filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

44. At the time of manufacture and sale of the Gunther Tulip filter (2000 until Present), the Cook Defendants knew or should have known that the Gunther Tulip filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. Was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall; and/or

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

e. There were no clinical trials which adequately established the efficacy of filter in preventing pulmonary embolisms.

45. At the time of manufacture and sale of the Gunther Tulip filter (2000 until Present), the Cook Defendants knew or should have known that using the Gunther Tulip filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; thrombus, cardiac arrhythmia and other symptoms similar to myocardial infraction; perforations of tissue, vessels, and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical

procedures including general anesthesia, with the attendant risk of life threatening complications.

46. The Cook Defendants knew or should have known that consumers of the Gunther Tulip filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

47. The Cook Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Gunther Tulip filter in, among others, the following ways:

a. Designing and distributing a product which the Cook Defendants knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other devices available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre- and post-sale, Plaintiff, Plaintiff's physicians, Plaintiff's agents, or the general healthcare community about the Gunther Tulip filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre- and post-market testing of the Gunther Tulip filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Gunther Tulip filter;

g. Advertising, marketing, and recommending the use of the Gunther Tulip filter, while concealing and failing to disclose or warn of the dangers known by Cook Defendants to be connected with and inherent in the use of the Gunther Tulip filter;

h. Representing that the Gunther Tulip filter was safe for its intended use when, in fact, the Cook Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing to manufacture and sell the Gunther Tulip filter with the knowledge that the product was dangerous and not reasonably safe;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Gunther Tulip filter so as to avoid the risk of serious harm associated with the use of the Gunther Tulip filter;

k. Advertising, marketing, promoting, and selling the Gunther Tulip filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality-assurance program used in the manufacturing of the Gunther Tulip filter; and,

m. Failing to establish and maintain an adequate post-market surveillance program.

48. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

49. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss have yet to be determined.

COUNT II

STRICT PRODUCTS LIABILITY – FAILURE TO WARN

50. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

51. This action is brought under the Michigan Product Liability Act, MCLA §600.2945, et seq.

52. The Cook Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Gunther Tulip filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

53. At the time the Cook Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the Cook Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, the Cook Defendants

knew or should have known at the time they manufactured, labeled, distributed and sold the Gunther Tulip filter, which was implanted into Plaintiff, that the Gunther Tulip filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting in serious injuries.

54. Consequently, the Cook Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device.

55. The Cook Defendants Cook further had a duty to warn of dangers and proper safety instructions that they became aware of even after the device was distributed and implanted in Plaintiff.

56. Despite their duties, the Cook Defendants failed to adequately warn of material facts regarding the safety and efficacy of the Gunther Tulip filter, and further failed to adequately provide instructions on the safe and proper use of the device. These failures rendered the Cook filter unreasonably dangerous to Plaintiff.

57. No health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

58. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

59. Plaintiff and Plaintiff's healthcare providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

60. Therefore, the Gunther Tulip filter implanted into Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling, and/or instructions accompanying the product.

61. The Gunther Tulip filter implanted into Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by the Cook Defendants.

62. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss have yet to be determined.

COUNT III
STRICT PRODUCTS LIABILITY – DESIGN DEFECT

63. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

64. This action is brought under the Michigan Product Liability Act, MCLA §600.2945, et seq.

65. At all times relevant to this action, the Cook Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed, and sold into the stream of commerce the Gunther Tulip filter, including the one implanted in Plaintiff.

66. The Gunther Tulip filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left the Cook Defendants possession. In the alternative, any changes that were made to Gunther Tulip filter implanted in Plaintiff were reasonably foreseeable to the Cook Defendants.

67. The Gunther Tulip filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

68. The Gunther Tulip filter implanted in Plaintiff was defective in design in that its risks of harm exceeded its claimed benefits.

69. The Cook Defendants knew that safer alternative designs were available, which would have prevented or significantly reduced the risk of the injury

presented by the Gunther Tulip filter. Further, it was economically and technologically feasible at the time the filter left the control of the Cook Defendants to prevent or reduce the risk of such a dangerous event by application of existing, or reasonably achievable, scientific knowledge.

70. Plaintiff and Plaintiff's healthcare providers used the Gunther Tulip filter in a manner that was reasonably foreseeable to the Cook Defendants.

71. Neither Plaintiff, nor Plaintiff's healthcare providers, could have, by the exercise of reasonable care, discovered the device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

72. The defective design of the Gunther Tulip filter was a producing cause of Plaintiff's injuries.

73. As a result of the Gunther Tulip Filter's defective design, Plaintiff has suffered and will continue to suffer serious medical complication for which the solution and ultimate economic loss have yet to be determined.

COUNT IV
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

74. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

75. This action is brought under the Michigan Product Liability Act, MCLA §600.2945, et seq.

76. The Cook Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Gunther Tulip filter that was implanted into Plaintiff.

77. The Gunther Tulip filter implanted in Plaintiff contained a condition or conditions, which the Cook Defendants did not intend, at the time it left the Cook Defendants' control and possession.

78. Plaintiff and Plaintiff's healthcare providers used the device in a manner that was reasonably foreseeable to Cook Defendants.

79. As a result of this condition or these conditions, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

80. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss have yet to be determined.

COUNT V
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

81. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

82. Defendants actions, as alleged herein, constitute a breach of the implied warranty of merchantability under MCLA §440.2314.

83. At all times relevant to this action, the Cook Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the Gunther Tulip and Celect IVC filters for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

84. At the time and place of sale, distribution, and supply of the Cook Gunther Tulip IVC filter to Plaintiff by way of Plaintiff's healthcare providers and medical facilities, the Cook Defendants expressly represented and warranted, by labeling materials submitted with the product, that the Cook filter was safe and effective for its intended and reasonably foreseeable use.

85. The Cook Defendants knew of the intended and reasonably foreseeable use of the Gunther Tulip filter at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

86. The Cook Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's healthcare providers, that the

Gunther Tulip filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

87. The representations and implied warranties made by the Cook Defendants were false, misleading, and inaccurate because the Gunther Tulip filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the Gunther Tulip IVC filter from the Cook Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

a. It was designed in such a manner so as to be prone to an unreasonably high rate of failure, including fracture, migration, excessive tilting, causing thrombosis and/or perforation of bodily organs;

b. It was designed in such a manner so as to result in an unreasonably high rate of injury to the organs and anatomy; and,

c. It was manufactured in such a manner so that the Gunter Tulip filter system was inadequately, improperly and inappropriately prepared and/or finished, so as to be prone to an unreasonably high rate of failure and/or causing the device to fail.

88. Plaintiff and Plaintiff's healthcare providers reasonably relied on the superior skill and judgment of the Cook Defendants as the designers, researchers and manufacturers of the product, as to whether the Gunther Tulip filter was of merchantable quality, safe and fit for its intended use and also relied on the implied

warranty of merchantability and fitness for the particular use and purpose for which the Gunther Tulip IVC filter was manufactured and sold.

89. The Cook Defendants placed the Gunther Tulip filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Gunther Tulip filter was manufactured and sold.

90. The Cook Defendants breached their implied warranty because their Gunther Tulip filter was not fit for its intended use and purpose.

91. As a direct and proximate result of the foregoing negligent acts and omissions by the Cook Defendants, Plaintiff has suffered a serious medical complication for which the solution and ultimate economic loss have yet to be determined.

COUNT VI
FRAUD AND NEGLIGENT MISREPRESENTATION

92. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

93. At all times relevant to this cause, and as detailed above, the Cook Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed

to disclose material information concerning the Gunther Tulip filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. safety of the Gunther Tulip filter;

b. efficacy of the Gunther Tulip filter;

c. rate of failure of the Gunther Tulip filter; and,

d. approved uses of the Gunther Tulip filter.

94. The information distributed by the Cook Defendants to the public, the medical community and Plaintiff's healthcare providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and omitted and concealed the truth about the dangers of the use of the Gunther Tulip filter. These materials included instructions for use and warning document that was included in the package of the Gunther Tulip filter that was implanted into Plaintiff.

95. The Cook Defendants' intent and purpose in making these representations was to deceive and defraud the public and the medical community, including Plaintiff's healthcare providers and Plaintiff's agents; to gain the confidence of the public and the medical community, including Plaintiff's healthcare providers and Plaintiff's agents; to falsely assure them of the quality of the Gunther Tulip filter and its fitness for use; and to induce the public and the medical

community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Gunther Tulip filter.

96. The foregoing representations and omissions by the Cook Defendants were in fact false. The Gunther Tulip filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Gunther Tulip filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

97. In reliance upon the false and negligent misrepresentations and omissions made by the Cook Defendants, Plaintiff, Plaintiff's agents, and Plaintiff's healthcare providers were induced to, and did use the Gunther Tulip filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

98. The Cook Defendants knew and had reason to know that Plaintiff, Plaintiff's healthcare providers, Plaintiff's agents, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by the Cook Defendants, and would not have prescribed and implanted same if the true facts regarding the device had not been concealed and misrepresented by the Cook Defendants.

99. The Cook Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the Gunther Tulip filter.

100. At the time the Cook Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Gunther Tulip filter, Plaintiff, Plaintiff's healthcare providers and the Plaintiff's agents were unaware of said the Cook Defendants' intentional and negligent misrepresentations and omissions.

101. Plaintiff's healthcare providers, Plaintiff's agents, and the general medical community reasonably relied upon the foregoing misrepresentations and omissions made by the Cook Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Gunther Tulip filter.

102. Plaintiff's healthcare providers and Plaintiff's agents' reliance on the foregoing misrepresentations and omissions by the Cook Defendants was the direct and proximate cause of Plaintiff's injuries as described herein. As a result of the Cook Defendants' misrepresentations and omissions, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

COUNT VII
MCLA §600.2949A – KNOWLEDGE OF DEFECTIVE PRODUCT

103. Plaintiff incorporates by reference all preceding paragraphs.

104. On information and belief, Defendant had actual knowledge that the Gunther Tulip IVC filter implanted in Plaintiff was defective and that there was a substantial likelihood that this defect would cause injury, and Defendant willfully disregarded that knowledge.

105. As a direct and proximate result of Defendants' action, Plaintiff sustained the injuries and damages described above.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff, Ernetta Simpson, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all Cook Defendants on all causes of action of this Complaint, including but not limited to:

   1. Physical pain and suffering in the past and which, in reasonable probability, he will continue to suffer in the future;

   2. Physical impairment and incapacity in the past and which, in reasonable probability, he will continue to suffer in the future;

   3. Mental anguish in the past and which, in reasonable probability, he will sustain in the future;

   4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future;

5. Disfigurement in the past and which, in reasonable probability, he will continue to suffer in the future; and,

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of Michigan as authorized by law on the judgments entered in Plaintiff's behalf; and,

d. Such other relief the court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands trial by jury on all issues.

SOMMERS SCHWARTZ, P.C.

DATED: June 5, 2020

/s/ Jason J. Thompson
Jason J. Thompson (P47184)
One Towne Square, 17th Floor
Southfield, MI 48706
Telephone: (248) 355-0300
jthompson@sommerspc.com

DALIMONTE RUEB STOLLER, LLP

/s/ John Dalimonte
John Dalimonte
85 Devonshire St, Suite 100
Boston, MA 02109
Telephone: (617) 302-9900
john@drlawllp.com

ATTORNEYS FOR PLAINTIFF